INTERVIEW

The world is finding it harder to breathe – an increasing global incidence of respiratory diseases, such as asthma and chronic obstructive pulmonary disease, is driving demand for therapies. Simultaneously, greenhouse gas emissions continue to rise, so the pharma industry must consider how to produce much-needed nasally delivered and orally inhaled medicines whilst minimising environmental impact. In this interview, Louise Righton, Head of Strategic Marketing, and Benedicta Bakpa, Head of ESG, both at Bespak, discuss the many different aspects involved in driving sustainability in inhaled drug delivery – and the next steps going forward.

LOUISE RIGHTON, HEAD OF STRATEGIC MARKETING

Louise Righton is Head of Strategic Marketing at Bespak. She has worked in the pressurised metered dose inhaler (pMDI) industry for more than 20 years in global marketing, commercial and government affairs roles. A graduate in Industrial Management, a Chartered Marketer and a Fellow of the Chartered Institute of Marketing, Ms Righton also holds a master's degree in Strategic Marketing Leadership. She is a board member at the International Pharmaceutical Aerosol Consortium and is committed to leading the change to sustainable pMDIs.

BENEDICTA BAKPA, HEAD OF ESG

Benedicta Bakpa is the Head of ESG at Bespak, bringing with her 15 years of experience in environmental management and sustainability across multiple sectors. She specialises in net zero carbon initiatives, helping organisations achieve their carbon reduction goals and contribute to a more sustainable future. Ms Bakpa has successfully led the implementation of numerous environmental and social value initiatives for companies in Africa, the Middle East and the UK. She holds a master's degree in Applied Environmental Economics from Imperial College London (UK) and a certificate in Business and Climate Change from the University of Cambridge (UK). Ms Bakpa is a Chartered Environmentalist and a full member of the Institute of Environmental Management and Assessment.

Q The prevalence of respiratory diseases around the world is growing. How does this impact the inhaled drug development industry?

LR To answer this question, we first need to understand why the prevalence is increasing. There are several contributing factors. Firstly, airborne pollution plays a role in the incidence of respiratory diseases such as asthma, and greenhouse gases have a major impact on air quality. The ageing population is another key driver because, as people age, they are more likely to suffer from chronic obstructive pulmonary disease (COPD). Finally, access to healthcare is thankfully continuing to increase, meaning more patients are able to be accurately diagnosed.

BB To add to that, global health initiatives have helped increase the awareness of respiratory diseases and their impact, focusing on early diagnosis and access to treatment so that more people can manage their symptoms themselves. Consequently, there is an increased demand for these drugs, particularly in developing countries. These countries are an important emerging market, as chronic respiratory diseases can represent a significant challenge to public health due to their frequency and severity, and the economic impacts of managing them.

LR As a result of these factors, there is increasing demand for pressurised metered dose inhalers (pMDIs), as this format of inhaled therapy is accepted by patients and cost effective for providers. Sustainability is also intrinsically linked with patient outcomes; for example, taking action to reduce pollution will help to mitigate one of the factors contributing to respiratory diseases. Therefore, with the number of pMDIs consumed every year growing, we have to find ways to increase

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sustainability and minimise the plastics and propellant gases released into the environment. Beyond this, ultimately, the patient with the lowest carbon footprint is a well-controlled patient. Access to early diagnosis, the right medication and clear guidance on how to use it effectively can all help to manage symptoms and prevent patients ending up in hospital, where their carbon footprint significantly increases.

Q What measures is the inhaled drug development industry implementing to achieve improved sustainability?

LR The big change we're focusing on as an industry is the phasing out of the hydrofluoroalkane (HFA) propellants that are currently used in pMDIs, due to their a high global warming potential (GWP). The industry is currently in the process of transitioning to two greener alternatives: HFA-152a and HFO-1234ze. This change will require significant investment in knowledge and infrastructure, as well as effective collaboration to ensure a smooth transition. Overall, we need to maintain the supply of life-saving pMDIs for patients, whilst also making sure that they comply with new regulations and reduce environmental impact.

We must also consider the materials and processes involved in manufacturing inhaled drug products. In particular, many of these devices are made from moulded plastic, so reducing this is a key step. Looking further ahead, we can work towards more reusable and reloadable devices, as well as incorporating more sustainably sourced materials. In addition, we can optimise the manufacturing processes themselves. By updating facilities and operations with the environment in mind, we can build sustainability throughout the entir supply chain.

BB Whilst it is key to think about the whole supply chain, cradle-to-grave product lifecycle assessments (LCAs) can be a useful way of understanding the environmental impact of a product and areas for improvement. When considering every step, from the raw materials through to the product's disposal, we can identify areas where the environmental impact can be reduced.

Another approach that will be important is embedding socio-economic factors into overall business practices. This includes corporate social responsibility (CSR) initiatives that raise environmental awareness with employees, as well as patients and wider communities. Similarly, holistically integrating sustainability into corporate strategy and decision-making processes will help ensure long-term environmental responsibility.

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Q How does the growing focus on sustainability impact companies developing inhaled drugs?

BB Drug developers will be exposed to new market and regulatory pressures along with increasing patient expectations – everyone is looking for the eco-friendly option. But there is also a need to strike a balance between implementing sustainable practices and working towards operational efficiency, all whilst maintaining a profit. Similarly, managing stakeholder interests can be a challenge. Drug developers must consider the interests of investors, patients, prescribers, employees and regulators, understanding how each stakeholder can support sustainable initiatives. As a result of these pressures, organisational changes may be needed to transition to sustainable practices, which may require a lot of effort and resources to implement.

LR In addition, from a drug-device standpoint, companies developing a new medicine must consider the delivery system both in terms of what is most effective and appropriate for the target patient population and also from an LCA perspective. Companies updating an existing medicine might look to add features that impact upon sustainability metrics, such as dose counters or reloadable devices, or might consider their use of materials, such as the packaging. Whilst priorities will differ, ultimately, all developers will be looking to differentiate their product, and so will be driven to continually broaden their thinking and explore how we can keep doing better.

Q What role do contract development and manufacturing organisations (CDMOs) play in supporting sustainability in the industry?

LR I think CDMOs have a huge part to play in the transition, such as proactively investing in development and full commercial supply capabilities with both of the new greener propellant options to help as many companies transition as quickly as possible. For example, at Bespak, we have recently invested in expanding our capabilities with the installation of new high-speed filling lines for commercial manufacturing with low-GWP propellants, as well as clinical supply capabilities. This reflects the unique role that CDMOs play, providing flexible capacity both now and in the longer term, coupled with the know-how to support manufacturing with new materials. We bring proactivity, leadership and a willingness to invest in the future of the industry.

BB The transition will draw on a range of capabilities that CDMOs can support the industry with, including experienced supply chain management. For example, a CDMO can help scale up production of low-GWP pMDIs and prepare customers for commercialisation. They are experienced in maintaining product quality and consistency, and also in managing the logistics associated with new propellants, such as sourcing, storage and handling, to minimise environmental impact.

LR There are also CDMOs that can help to speed up how companies navigate the shift by supporting them across multiple facets of their product transition. At Bespak, for example, we produce valves that are optimised, supply-assured and compatible with both new propellants, streamlining the product design process. Following significant investments, Bespak can now provide development services up to market approval for all pMDI formulations and propellants, supported by capacity for commercial supply.

BB CDMOs are also well positioned to lead best practice in terms of energy efficiency, waste reduction, water management and sustainable sourcing. The key steps here include integrating renewable energy sources, such as solar panels, into their operations to further reduce greenhouse gas emissions; aiming for lean manufacturing to reduce waste and minimise resource consumption; and implementing water conservation techniques to reduce water use in the manufacturing process. Enhancing sustainable sourcing of raw and packaging materials and optimising logistics can also reduce emissions from transportation and ensure sustainable practices throughout the supply chain.

LR Another approach CDMOs can incorporate is manufacturing control technology, such as via the digitisation of manufacturing facilities. These technologies enable the continual monitoring of production to provide very early warning of any defects starting to occur. At Bespak, this is something we are currently implementing at our King's Lynn (UK) site. The approach helps to increase the quality and consistency of our output – supporting delivery of customer orders on time and in full – and, in doing so, reduce waste and minimise environmental impact.

LR Lastly, CDMOs that operate across R&D, finished product manufacturing and device design and industrialisation must have a comprehensive view of the regulatory landscape. They can, therefore, support and advise customers on multiple such aspects, from regional and global environmental legislation right through to the intricacies of pharmaceutical and medical device regulation.

BB Understanding the intricacies of the global regulatory requirements related to environmental sustainability is really important. CDMOs can also consider compliance management to ensure that all manufacturing processes comply with current regulations and are prepared for any future changes. They can also help customers to navigate complex regulatory landscapes.

Q **What factors should drug developers take into consideration when working with a CDMO to develop a new medicine in line with evolving environmental regulations?**

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BB As we have discussed, there are many challenges in working towards sustainability, including the changing regulatory landscape and the significant cost of compliance, including how resource intensive it can be to update manufacturing processes and equipment. Collaboration and communication with stakeholders, such as regulators, investors and customers, are therefore vital in aligning interests on sustainability goals, prioritising continuous improvement and driving best practices.

LR I agree that collaboration is absolutely critical. Developers should look for a CDMO that is driven to bring its customers the best, most efficient, most robust service to help them with everything they need. Bespak puts a lot of emphasis on building the right partnerships – for example, with clinical trials experts and specialists in specific technology development. We also have sustainability at the core of our mission and vision, so we are well positioned to help give drug developers the competitive edge to succeed in this evolving landscape.

Q **How do you think sustainability pressures will shape the industry in the short and long term?**

BB Looking to the next three to five years, I think we can expect increased standards of regulatory compliance – for example, enhanced reporting processes and transparency. We will likely also see a shift towards more sustainable packaging, reducing the plastic footprint whilst maintaining product integrity. I also anticipate more CDMOs being fully reliant on renewable energy. Longer term, I think we will see an increased focus on education, with investment in thought leadership on sustainability for patients and providers through both patient education and awareness, and patient and provider engagement. By taking these steps, CDMOs can not only reduce their environmental impact but also position themselves as leaders in the movement towards a more sustainable healthcare system.

LR I agree that there will be increased emphasis on keeping the patient at the centre. Drug developers will need to think about clinical outcomes for patients and environmental outcomes in tandem, and how they can optimise both. I think we can also expect a more holistic approach to reducing the environmental footprint – for example, with biologic treatments that patients can administer at home rather than having to travel to a clinic. I am also hopeful that we will see increased funding for research into long-term sustainable commercial practices and further collaborations beyond the pharmaceutical sector.

ABOUT THE COMPANY

Bespak is a global CDMO focused on inhaled and nasal drug delivery devices and drug-device combination products. The company develops and manufactures finished pharmaceutical products, as well as being a leading global supplier of drug delivery devices and componentry to the pharmaceutical industry.

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